DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

October 30, 2002

Louis M. Kerpan, Jr.
Director of Operations
R. E. Rogers, Inc.
23900 Hawthorne Boulevard, Suite 200
Torrance, California 90505

Dear Mr. Kerpan:

Thank you for your letter to me of October 16, 2002, concerning the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Your letter raises important issues about the application of this law to trade shows that involve samples of food that are brought in from other countries.

As you may know, FDA is planning to publish proposed rules concerning registration, record keeping, prior notice of imports and administrative detention. We have already opened dockets on each of these areas and have already begun to receive comments. Because your letter makes comments on each of these topics, I am forwarding your letter to be included as a comment in each docket.

When our proposals publish, which we hope to be within the next couple of months, I would encourage you to make specific comments based on the actual content of those proposals. I would also encourage you to think about the potential for terrorist activities that could be conducted in association with your trade shows and how you might help us to protect the public.

Sincerely yours,

L. Robert Lake

L. Robert Lake
Director of Regulations and Policy
Center for Food Safety
and Applied Nutrition

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UNITED STATES

October 16, 2002

Mr. L. Robert Lake, Esq.
Director of Regulations and Policy
Mail Code HFS-4
Food & Drug Administration
5600 Fishers Lane
Rockville, MD, 20857

Re: Comments and Request for Guidance

Ref: Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188)

Dear Mr. Lake,

My name is Louis M. Kerpan Jr. and I am the Director of Operations for R.E. Rogers Inc. We are involved in the international exhibition customs brokerage, international freight forwarding and transportation business. We act as the importer of record for many food and beverage shows in the United States. We are appointed by the owner or producer of the event as the 'official' broker or forwarder for the event to assist international exhibitors ship sample product to the event. I've listed several of the largest events we work on where large quantities of foreign food and beverage products are imported by our firm:

Winter Fancy Foods Show 2003, January 19-21, San Francisco, CA
Spring Fancy Foods Show 2003, May 5-7, Chicago, IL
Summer Fancy Foods Show 2003, June 29-July 1, New York, NY
http://www.fancyfoodshows.com/

The FMI Show, May 5-7, Chicago, IL
www.fmi.org

Numerous other tradeshows and exhibitions throughout the United States also have foreign exhibitors that bring product into the United States either for sampling by attendees at the event or for hospitality purposes when pitching some other product. Virtually every professional association and industry puts on a conference and tradeshow every one to three years somewhere in the United States. This is huge multi-billion dollar business that many Americans depend

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upon for their livelihood. As a matter of fact, I've met FDA personnel at shows such as the BIO event where we've acted as the official broker and forwarder.

Typically the international shipments for these events come in three main ways:

1. We consolidate large numbers of exhibitors, each with their small boxes of samples, at one point in the foreign country of origin and ship together to the United States. We then make one large entry with U.S. Customs and any other relevant agencies.

2. An exhibitor ships only their material and we make an entry only for that one exhibitor's material.

3. An exhibitor may send their samples via courier such as DHL, FedEx, UPS, etc. Typically we do not become involved in such entries.

In all cases, the amounts of product per exhibitor are quite small, are not considered 'commercial' quantities and are consumed at the event. Leftovers are typically destroyed, given to charity or retained by the U.S. office or agent of the exhibitor. We don't handle each and every international shipment to the show, as our service is not exclusive. The exhibitors are free to use any broker or forwarder they wish.

For all of the events that we work on, we typically obtain the official tradefair designation from the U.S. Department of Commerce as allowed by the Trade Fair Act of 1959. This allows for the temporary duty free entry of goods into the United States for the purposes of exhibit at events so designated. For food and beverage samples, we've used this document to obtain flexibility from the various field offices of the various agencies. We also obtain from the Bureau of Alcohol, Tobacco & Firearms a waiver from the requirement for label approval and an importer's basic permit for alcoholic beverages. I've attached copies of these documents for the upcoming Winter Fancy Foods 2003 event for your review.

For each food event that we are appointed as the official broker or forwarder, we publish 'international shipping instructions'. These serve as a basic primer for foreign exhibitors shipping product to the United States for the event. We try to inform the shipper's of the various rules and regulations of the United States so that they can not only get their samples to the show on time but also to gain some understanding of the regulatory expectations foreign products must meet if a U.S. buyer is to show any interest.

Under current FDA regulation, there exists no formal acknowledgement or recognition of food and beverage products brought into the United States for tradeshows and exhibitions. We've dealt with this at a local level in the various

ports where the entries for these events are made. Each port has it's own policy and generally cooperates with us to insure that the samples get to the show on time provided that the items are not dangerous or questionable. For instance, in San Francisco, we file a letter with the Director (sample attached) and allow the FDA inspectors complete access to the freight and exhibitors before and during the event. In the ten years I've been with this company and working on these events in this matter, I can only recall a couple instances where the FDA has not released a shipment of sample product for our events.

The only real beef that we have with the current food import procedures is we do not see the benefit to anybody including the U.S. government, the public and ourselves for filing the amount of information necessary for these small sample shipments through the Import ABI system. We've asked about the establishment of a sample waiver for certified events but have never received any consideration.

However, I am quite concerned about the provisions of PL 107-188 on our operations for these events. Relative to tradeshows and exhibitions, this law is like using a paint roller when a small detail brush is called for to achieve the same level of safety for the food and beverage supply. I shall discuss my concerns by section and make suggestions:

Section 305 (Registration of Food Facilities).

For example, a unit of the Italian Government called the Italian Trade Commission sponsors and organizes a pavilion of Italian exhibitors at each Fancy Food show. This pavilion can contain hundreds of products from hundreds of producers. Typically, the Italian Trade Commission is signing up exhibitors up to the last minute for the event. This section requires that all of these exhibitors would have to register with the FDA.

If an exhibitor signs up for the show at the last minute and is not registered, then it is possible that they cannot display or have their product sampled at the show. As the process for registration is unknown at present in terms of cost, amount of paperwork and length of time, this can discourage participation in the events or cause an exhibitor who has spent a great deal of money on a booth, plane tickets, etc. to not be able to show their product. This could result in a real economic hardship for the exhibitor and, in retaliation, foreign governments could begin to impose similar requirements on U.S. exhibitors going to events in other countries. As we also handle shipments of U.S. companies participating in foreign tradeshows, we know this to be a real concern.

One of the reasons that exhibitors invest their time and money in tradeshows is to test the market for interest in their product and to find trusted agents, distributors or buyers. If registration is required for sample shipments and if registration is lengthy, expensive and inefficient, this will also stifle innovation in

the food and beverage industries, reduce choice to the American consumer and discourage free trade.

We suggest that a waiver program for international sample shipments for tradeshows be developed. To be eligible for a waiver, the following requirements should be met:

1. The event must be certified as an official tradefair under the Tradefair Act of 1959.
2. The FDA must be allowed complete access to the cargo and the exhibitors at the showsite.
3. The event must designate an agent within the U.S. to retain all records of import entries for at least five years made for that event through their 'official' broker or forwarder.
4. The operator or owner of the event must submit to the FDA in advance a complete exhibitor list or catalogue of the event that lists the exhibitor's name, address, phone, fax, e-mail and description of the products they wish to show. The operator or owner of the event must comply with any request from the FDA for any copies of exhibitor contracts and attendee lists. The operator or owner agrees to keep the records for at least five years.
5. Any goods found by the FDA to present a danger to any human or animal may be removed or detained if credible evidence or information is presented by an officer or qualified employee of the FDA.
6. All other import requirements and processes must be met or followed.
7. Only small, non-commercial quantities product may be entered into the United States sufficient for display and sampling at the event.
8. The owner or organizer of the event will designate the location of any advance receiving warehouses where product would be stored prior to move-in at the showsite.

The advantages of this approach are as follows:

1. The registration database is not cluttered with information from one-time shippers of small sample shipments.
2. If some of the exhibitors participate in more than one event or if they forget their registration identifier or code between events, then this avoids duplicated entries into the database.
3. The local field office has immediate access to the freight and the exhibitor as well as information about the exhibitor without the expenditure of large amounts of time and money by both the FDA and the exhibitor.

If the intent of this section is for some sort of record to be kept of each exhibitor who ships food to a tradeshow or exhibition, then a waiver achieves this intent without spending a lot of money and creating a new barrier to trade.

Section 306 (Establishment and Maintenance of Records).

Using our example of the Fancy Foods shows, we know the immediate previous sources for each shipment and the immediate subsequent recipient for each shipment. It is often the same entity unless they have an agent, distributor or broker represent them at the event. In any case, we have first hand knowledge of these entities. Furthermore, each attendee who may possibly sample the product of the exhibitor must register with the event operator or owner before receiving a badge to enter the exhibit area. These events are not open to the general public.

Each exhibitor at each tradeshow must contract with the owner or producer of the event for the booth space. Before space is granted at most events, the exhibitor must qualify. The product must fit in with the nature of the show. For instance, the producer of Captain Crunch won't show this product at a natural foods event. After the exhibitor qualifies and a contract for space is made, then each exhibitor must submit information for inclusion in the event's catalogue.

Under the waiver program suggested above, the FDA would achieve the intent of this section, a chain of custody, without any cost by using processes already used by the owner or producer of the events for other purposes.

Section 307 (Prior Notice of Imported Food Shipments).

Again using our example of the Fancy Foods shows, these events have been held in the same location around the same time of year for many years. They advertise in relevant industry publications and always make the local news with the mayor or other VIP seen sampling some food or beverage product. Restaurants, taxi companies, hotels and other entertainment companies gear up for these events because of the amount of business that the exhibitors and attendees generate. For food events in particular, it is highly likely that local FDA staff receive invitations to attend! The point is that these events are well known and planned years in advance.

The intent of prior notification is to prepare local field offices to target suspicious shipments from questionable sources. Under a waiver program as proposed above, the local FDA field office could be notified in the same manner that the U.S. Department of Commerce notifies the U.S. Customs Service when the official tradefair designation has been given to a particular event. In conjunction with the information that accompanies the application for a tradeshow waiver, the FDA knows or has access to the name of each exhibitor, their address, the importer, the country of origin, the port of entry and a description of what the exhibitor intends to show in general terms.

By having complete access to the cargo and the exhibitor before and during the show in one location with access control, the FDA is given ample opportunity to focus and intensively examine those shipments that are most interest to the FDA without creating a huge paperwork burden on the local field staff.

Section 303 (Administrative Detention).

Exhibiting in a tradeshow in a foreign country is expensive and frightening. You don't know the language, your biological clock is messed up, you're nervous about meeting existing and prospective buyers and you probably forgot something at home that you really need. Often, first time shippers to the United States may not adequately describe their goods on their documents. For instance, when shipping small yellow peppers packed in brine or vinegar, our Italian exhibitors may call the product pepperoni. In some parts of Italy and New York, this is a correct description or name. However, many other people in the U.S. would be thinking about a meat product. This could cause a long and costly delay in the clearance of the shipment due merely to a communications breakdown. The exhibitor misses the event for no good reason.

Under a waiver program for tradeshows, the FDA would be given ample opportunity to detain or sample any shipment that is deemed by a FDA officer or qualified employee as harmful to humans or animals through complete access to the showsite before and during the event. Decisions could be made quickly through direct inspection of a product. An advantage of tradeshow material is that the FDA also has direct access to the producer, processor or manufacturer of the product on the show floor. The FDA and the exhibitor have an opportunity to learn more about the product, the regulations, the processes and people that go into making the product. The exhibitor learns and the FDA may avoid making an egregious error that is costly for the exhibitor.

The establishment of a tradeshow waiver program by the FDA would achieve the following objectives:

1. Compliance with the intent of Congress regarding the protection of the food and beverage supply in an efficient and cost effective manner.
2. Avoid the construction of a non-tariff barrier to trade that could have potential adverse impact on U.S. food and beverage exporters, farmers, producers and distributors.
3. Standardizes the approach of the FDA around the country regarding international shipments to tradeshows.
4. Uses systems and practices already in place in a new way to accomplish new goals.
5. Reduces the amount of paperwork to a manageable level while retaining complete access to relevant information necessary for any FDA action.

6. Provides the FDA an opportunity to review, inspect and learn about new food and beverage products often before they come to market.
7. Saves the FDA money in terms of resources, staff, administrative and legal action, systems and procedures without sacrificing access and control.

Thank you for this opportunity to make our views known. We do hope that you seriously consider our proposal. If you require further information, please don't hesitate to contact me.

Regards,

Louis M. Kerpan Jr.
Director of Operations

LMK/ftc
Attachments